REMARKS

Priority

The Office Action incorrectly alleges that foreign priority cannot be granted because no certified translation was submitted. A certified copy of the foreign application specified in 35 U.S.C. 119(b) or PCT Rule 17 must be filed, but a translation thereof is not a requirement for claiming benefit of a foreign application. See, e.g., 37 CFR § 1.55. Typically, a verified translation of a priority document is filed when needed to overcome the date of a reference relied upon in a rejection.

The Rejections Under 35 USC § 112, second paragraph

The term "derivatives" has been deleted from the claims, rendering this rejection moot.

The Rejections Under 35 USC § 112, first paragraph

The term "derivatives" and "solvates" have been deleted from the claims. However, a new claim is added which recites a "solvate," and another claim is added which recites certain more specific types of solvates, i.e., a "mono- or dihydrate or alcoholate." Thus, the rejection regarding "derivatives" is moot, and comments on the rejection of the term "solvates" are provided below.

The Office Action alleges that "none of the examples provided solvates." However, the Office Action ignores that the examples are not drawn to the preparation of solvates. Merely because the preparation of solvates is not exemplified, that does not provide basis for allegations that the preparation of solvates is not enabled.

This is especially so because there is no requirement for examples at all in patent applications. See, for example, *In re Marzocchi*, 169 U.S.P.Q. 367 (1971), stating that "an enabling teaching is set forth, either by use of illustrative examples or by broad terminology, is of no importance." (Emphasis added.) The MPEP in agreement with this by stating that "compliance with the enablement requirement of 35 U.S.C. 112, first paragraph, does not turn on whether an example is disclosed." (Emphasis added.) See MPEP § 2164.02.

The Office Action points to Braga, p. 2640, stating that "solvate formation can be a nightmare because it is extremely difficult to predict ..."

However, something being a "nightmare" or "extremely difficult to predict" is not the standard for enablement rejection. Just because there may be some difficulties in the process

generally, does not mean that it would pose an undue amount of experimentation to prepare a solvate of the claimed compounds.

While the amount of work to prepare solvates of the compounds of the invention may require some effort, or maybe even considerable effort (although not admitted), no undue experimentation is required in the preparation of solvates. "The test of enablement is whether one reasonably skilled in the art could make or use the invention from disclosures in the patent coupled with information known in the art without undue experimentation." *United States v. Telectronics*, 8 USPQ2d 1217 (Fed. Cir. 1988). One of ordinary skill in the art merely through routine laboratory efforts can take various compounds of the invention, which are enabled, bring them together with various solvents, e.g., water, various alcohols, etc., and check whether solvates have formed. This type of work is merely routine laboratory work and does not require undue experimentation.

Moreover, as discussed in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988), the "test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine." The tasks involved in forming solvates are routine, i.e., the addition of various solvents to the enabled compounds and checking whether a solvate formed, even if the formation of solvates has some amount of unpredictability.

Reconsideration is respectfully requested.

The Rejections Under 35 USC § 102

The Office Action alleges that the claims are obvious over EP '838 (Supplemented with CA 123:198635 to more readily illustrate the species of the reference) in view of US '401.

EP '383 is in German. An English language equivalent is filed herewith, i.e., CA 2,118,375.

The Office Action alleges that EP '383 generically discloses the claimed compounds. Applicants respectfully disagree. All the compounds of this reference are meta substituted piperidine compounds, while the claimed compounds are para-substituted piperidine compounds. Compare general formula I of the reference with the claimed formula I of this application. Thus, even in the broadest disclosure of EP '383, the claimed invention is not disclosed. Additionally, as admitted by the Office Action, all the species disclosed in EP '383 have identically substituted phenyl groups, while the claimed compounds have a

sulfonamide substituent on one of the two phenyl groups, and a different set of possible substituents on the other phenyl group.

The Office Action then points to US '401 alleging that this reference teaches similar compounds to one of the species of EP '838 which can be asymmetrically substituted, and then alleges that the modification of one proven compound with attributes of another proven compound is prima facie obvious. Both allegations are incorrect.

US '401 tests several compounds of US 4,959,366 and a compound of EP '838. See disclosure on page 10, first column, the last three lines before the structures of the tested compounds are disclosed. Merely, compounds from two different sources are provided in a single list. Nothing in this disclosure teaches or even remotely suggests that any of the compounds should be modified in any way, including taking attributes of any one of those compounds and using the same on another one within the list.

Additionally, these compounds are not at all alike, i.e., they are not similar. For example, none of the compounds other than the compound of EP '838 contains three independent rings. Additionally, none of the compounds other than the compound of EP '838 contains a piperidine group.

Moreover, the broad allegation that modification of one proven compound with attributes of another proven compound is prima facie obvious is incorrect and legally indefensible. Controlling case law held exactly the contrary to what is alleged here. See *In re Jones*, 958 F.2d 347, 21 U.S.P.Q. 2d 1941 (Fed. Cir. 1992) and *In re Baird*, 16 F.2d 380, 29 U.S.P.Q. 2d 1550 (Fed. Cir. 1994).

Note in this regard, particularly, the analysis used by the Federal Circuit in *Jones*. The group at issue in *Jones* had the structure

$$-NH_2-CH_2CH_2-O-CH_2CH_2OH.$$

The PTO tried to rely on the single reference's compound having two CH_2CH_2OH groups attached to a single N atom, instead of linked together as shown above. The Court stated that one could not ignore the fact that the two CH_2CH_2OH groups were not joined together to form the ether linkage-containing group required in the claim. One could not simply rely on the "$-CH_2CH_2O-$" features of the reference; one had to consider the entirety of the structure involved. The Patent and Trademark Office also tried to rely on a morpholino group in the single reference wherein the nitrogen atom has two ethyl groups bonded to it and linked to each other by a single oxygen atom, thereby allegedly providing the "missing" ether oxygen noted above. Again, the Court stated that one could not ignore the entirety of the structure,

i.e., the fact that this prior art group compound was cyclic. One could not apply components of its structural features in isolation apart from the group's overall structure. Other similar analyses were rejected by the Court.

Likewise here to the situation in *Jones*, the disclosure of US '401, listing various specific compounds of US '366 and EP '838, does not give basis to the allegation that because certain US '366 compounds have different substituents on their two phenyl groups, the disclosed EP '838 compound too should have different substituents on its two phenyl groups. One cannot ignore the entirety of the structure of any given compound, and thus, cannot apply components of the structural features of any one of them in isolation apart from its overall structure and apply said component to another different compound. Such piecing together of an invention from various differing structures is improper under well settled precedents.

Additionally, no teaching or motivation is provided in US '401 or in any of the references that there is a need or desire to modify the compound of, e.g., EP '838, in view of any other disclosed compound. For example, nothing in any of the references teaches or suggests that compounds with different substituents on the two phenyl groups are better for any reason. Moreover, it is entirely unclear from the references that even if such piecing together would be performed, whether the resultant compounds would have the desired properties. All the compounds in US '401 next to the compound of EP '838 are very different as discussed above, e.g., different number of cyclic structures, etc. And, some of them are identically substituted while others are not.

Disclosure of particular generic formulae and/or species with their particular set of structural components, under *Baird* and *Jones*, does not motivate one of ordinary skill in the art to select various structural features from different compounds or from different generic formulae in isolation and apply them to other compounds or other generic formulae.

For all the foregoing reasons, the claims are not obvious.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,

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